State of Washington Department of Labor and Industries
Office of the Medical Directory
Technology Assessment
Microprocessor-Controlled Prosthetic Knees

I. Introduction

A number of different prosthetic designs and supplements are available to amputees depending on the amputation level. The simplest and least expensive type of prosthetic knee has a single axis hinge allowing the knee to bend. An optional adjustable friction cell may provide some damping of swing phase motion by pressing against the knee axle. An additional spring loaded or elastic extension helps limit heel rise and extends the shin before heel strike. Because proper knee swinging occurs at one fixed cadence, the design may overly restrict athletic amputees.

Adding fluid control units to a knee frame helps to control swing phase. The pneumatic or hydraulic fluid-controlled knees have pistons that adjust the swing phase resistance as gait changes. Pneumatic control cylinders contain compressible air, and hydraulic dampers contain silicone oil to control cadence. Because knee resistance responds automatically to changing walking speeds, an amputee may engage in a range of activities. However, the heavier fluid-controlled units cost more than simpler prosthetic designs.

Prosthetic knees may include built-in stance phase stability. The rarely used manual locking knee provides the greatest amount of stability, but results in a stiff legged gait requiring the most effort. An alternative, the stance control or safety knee, uses the body’s weight to engage a friction brake to stop knee motion. The spring-loaded brake binds when loaded during stance and releases during swing. Therefore, when an amputee applies little or no weight to the prosthesis, stance control knees swing freely. However, brake stability interferes with initiating knee flexion during preswing at a normal walking pace. This popular type of control suits elderly patients and ambulators who walk slowly.

Another knee design is the polycentric knee, or 4-bar knee. The 4-bar knee prosthesis has 4 points of rotation connected by a linkage bar. An inverse relationship exists between knee flexion and prosthesis length. As a result, this design offers greater toe clearance at midswing. Additional benefits of the 4-bar knee include improved sitting appearance as well as increased stance stability. The complicated polycentric design weighs more and may require more servicing. Hybrid polycentric knees also offer fluid swing phase controls. The 4-bar knee may best facilitate walking at moderate or higher paces. (Catholic undated) (Michael 1999a) (Michael 1999b)

II. Microprocessor-Controlled Prostheses

Microprocessor-controlled prosthetic knees use computers to enhance basic mechanical knee designs. Otto Bock Orthopedic Industry produced in 1999 the 3C100 C-Leg, a microprocessor-controlled knee with both hydraulic stance and swing phase control. Charles A. Blatchford & Sons of Great Britain introduced a microprocessor-controlled Intelligent Prosthesis in 1993, an improved version called the Intelligent Prosthesis Plus in 1995, and the Adaptive Prosthesis in 1998.

Otto Bock's C-Leg has force sensors in the shin that use heel, toe and axial loading data to determine stance phase stability. A knee angle sensor provides data for control of swing phase, angle, velocity and direction of the moment created at the knee. Sensor technology adapts to movements by measuring angles and moments 50 times per second. The unit transfers information to the hydraulic valve allowing reaction to changing conditions. As a result, an individual's gait resembles natural walking on different types of terrain. The C-Leg uses a rechargeable battery that lasts 25 to 30 hours. If the battery remains uncharged, the knee joint goes into a safety mode operation. (Otto Bock Undated)

Endolite plans to begin marketing Blatchford's Adaptive Prosthesis in the United States in September 2002. The Adaptive Prosthesis uses 2 microprocessor-controlled motor valves to control a hybrid hydraulic and pneumatic system. The hydraulic system controls stance, flexion, and terminal impact. The pneumatic system controls swing phase, and extension assistance. The Adaptive Prosthesis also offers a voluntary locking mechanism for extended standing and a stumble control that responds to prevent knee buckling. The Adaptive Prosthesis has batteries that power the system for several months and a software design that prevents memory loss during battery replacement. (Blatchford Undated) (Pike 1999) (Schuch 1998)

III. Reason for Review

Due to recent requests for microprocessor-controlled knees, Occupational Nurse Consultants requested that the Office of the Medical Director conduct an assessment.

IV. Food and Drug Administration Status

In July 1999, the Food and Drug Administration (FDA) classified the C-Leg as a Class I device substantially equivalent to other devices in the "Assembly, Knee/Shank/Ankle/Foot, External" category.

The registered intended use statement reads that the C-Leg is "for use in the fitting of lower limb prostheses. It can be used by highly mobile individuals as well as those who need additional stance stability." (FDA 1999) Otto Bock also states that the C-Leg may benefit unilateral, transfemoral amputees weighing up to 220 pounds who have a moderate or higher (Level 2 or 3) functional level. Ideal candidates have mastered the use of a Mauch, CaTech, or 3R80 Stance and Swing Control Hydraulic Unit. (Otto Bock Undated)

Endolite has listed the Intelligent Prosthesis Plus and the Adaptive Prosthesis with the FDA under the Proprietary Name “Endolite Knee Shin.” (FDA 1994)

V. Review of Evidence

A. Otto Bock has provided 2 studies on the C-Leg, but the studies have not been published in peer-reviewed journals. The translated abstract from a published, German article is also summarized.

1. Investigators compared the C-Leg to other Otto Bock hydraulic knee joints, the 3R45 and the 3R80. (Kastner Undated) After receiving 10 minutes to accustom themselves to the joints, subjects underwent 4 tests.

Test	Subject’s Task	Measurement
Stance Phase Load	1. Walk across two plates that measure ground reaction forces.	1. Deviation ranges for the left and right feet to assess any asymmetries. 2. Average time and amount of loading to the heel and ball of the foot.
Swing Phase	1. Wear 6 markers on prosthesis and sound leg. 2. Walk on treadmill at 3, 4, and 5 km/h for 30 sec.	1. Marker displacement time variations 2. Angle progressions and deviation ranges for vertical thigh, knee, and ankle joint.
Uphill, Downhill	1. Walk uphill and downhill on treadmill for 5 minutes at speed of 3 km/h and 10% incline.	1. Heart rate.
1000 m Ground	1. Cover distance as fast as possible.	1. Heart rate: resting rate while sitting, exercising rate while walking, and recovering rate 3 minutes later. 2. Average gait speed.

Study Population: The study included 10 unilateral, above-knee amputees between the ages of 32 and 64 years who underwent amputations 2 to 37 years earlier.

Results:

Stance phase – Of the 10 subjects, only 3 clearly showed greater asymmetry while walking with the C-Leg. Researchers suggest that gait training would improve swing phase.

Swing phase – Researchers did not detect differences between the 3 prostheses for cycle time, cycle length, swing time, and stance phase time. No differences existed between the prostheses and sound leg for those parameters.

For the maximum flexion angle parameter, the C-Leg achieved the lowest average angle at each speed. At 3 km/h, the flexion angles for the C-Leg and the 3R80 were lower than for the sound leg. At 5 km/h, the C-Leg reaches the same angle as that of the sound leg.

For the maximum flexion speed parameter, the C-Leg had the lowest average speed suggesting smoother swing phase. The sound leg had a slower flexion speed compared to all 3 prostheses. The extension speed of the sound leg fell between the speed of the C-Leg and 3R80.

Uphill, downhill – The subjects' heart rate did not differ between the three prostheses. When going downhill, some subjects felt insecure with the C-Leg. Incorrect conclusion of the step-over-step resulted in the prosthesis remaining stiff at swing phase. Investigators suggest that gait training would provide a remedy.

1000 m ground test – The C-Leg achieved the fastest time by more than a minute, but results did not reach statistical significance. Gait with the C-Leg averaged 6.76 km/h.

Conclusion: The C-Leg provides advantages in swing behavior allowing a harmonic gait over a range of speeds.

2. The study examined the physiological costs of a hydraulic, single-axis joint (3C1) compared to the C-Leg. (Schmalz, undated) Subjects walked on a treadmill at three speeds: self-selected speed, 20% slower speed, and 20% faster speed. After 30 minutes, the subjects underwent the same test with the C-Leg.

   Investigators monitored heart rate, expiratory volumes, oxygen consumption (VO2), carbon dioxide emission (VCO2), and respiration quotients (RQ=VO2/VCO2). The mean value of the last minute of each speed was used for the evaluation.

   Study Population: The study included 6 trans-femoral amputees who regularly used the 3C1 joint. Subjects received the C-Leg several weeks before undergoing tests.

   Results: Mean VO2 decreased 4% to 7% with the C-Leg compared to the 3C1. Lower VCO2 values for the C-Leg resulted in RQ improvement of 5% to 11%. Energy expenditure reduction occurred more distinctly at slower speeds.

   Walking with the C-Leg resulted in a slightly slower heart rate.

   Conclusion: The C-Leg produces an energy expenditure benefit.

3. The abstract of a published, German article describes a study comparing a traditional prosthesis treatment to the C-Leg. (Stinus 2000) Researchers observed 15 C-Leg subjects for 6 to 14 months. The subjects then compared the C-Leg to previous fitted knee joints. Prosthetists and patients rated the C-Leg as "very good" and described a clear improvement to previous mechanical prosthesess.

B. Peer-reviewed journals have published 4 studies on the Intelligent Prosthesis (IP). The Medical Devices Agency in Great Britain also conducted an evaluation of IP.

1. Researchers used a questionnaire to survey 22 patients on their views of the IP compared to pneumatic swing-phase control joints. (Datta 1998) The survey consisted of closed questions with 5 possible responses and 2 open questions with space for comments.

   Study Population: The study included 22 unilateral, transfemoral amputees who switched from pneumatic swing phase control joints to IP. The fit, active subjects did not have stump problems. Sixteen subjects underwent amputation due to trauma. The group had an average age of 39.9 years and average time from amputation of 19.2 years (range 5 to 53 years). A mean of 17.4 months (range 7 to 41 months) elapsed from receiving the IP to answering the survey. Subjects did not receive special gait-reeducation after getting IP.

   Results:
   With the IP, the majority of subjects gave an “easier” rating to:
   - walking (95.4%)
   - walking on slopes and hills (59%)
   - walking on rough/uneven ground (63.6%)

   Subjects did not experience any differences between prostheses for walking up and down stairs. Subjects (81.8%) felt that they could walk further with IP. They also found that walking:
   - felt less tiring (95.4%)
   - felt more normal (95.4%)
   - appeared favorable to others (86.3%)

   Most subjects (81.8%) adjusted to the IP within a short time. When comparing IP to the standard prosthesis, most subjects rated IP as:
   - more mechanically reliable (63.6%)
   - improved (100%)

   One subject wanted to revert to the original prosthesis. Three subjects experienced battery failure, and one computer broke down.

   Conclusion: Patients show a strong preference for the IP when compared to pneumatic swing phase control in a survey.

2. A pilot study compared a conventional prosthesis to a microprocessor-controlled Intelligent Prosthesis (IP) by examining the cognitive demand of walking. (Heller 2000) Subjects wore the conventional prosthesis while walking for 60 seconds on a treadmill that varied its speed. While walking, the subjects performed either a simple or complex distracting task. Six weeks later, the subjects underwent the same test while using the IP.

Investigators calculated subject sway by analyzing the motion of a marker on the subject's forehead. After summing total marker displacement, researchers calculated velocity. They recorded the average velocity according to task and prosthesis. Finally, the researchers calculated the ratio of velocity during the simple task to velocity during the complex task.

Study Population: The ten unilateral transfemoral amputees were at least five years post amputation and had no stump problems.

Results: For all subjects, the ratios were 1.8% smaller for the IP than for the conventional prosthesis. Velocity for both tests averaged 212 mm/s for the conventional prosthesis and 185 mm/s for IP. Sway during the complex task was higher than during the simple task.

Conclusion: The microprocessor-controlled prosthesis did not require less cognitive demand than conventional prostheses.

3. The study compared pneumatic swing-phase control knees to IP by examining gait symmetry and energy expenditure. (Kirker 1996) Researchers reported gait symmetry as:

$$\frac{100[\text{prosthesis stride length - natural leg stride length}]}{\text{total stride length}}$$

Oxygen consumption measured energy expenditure.

Subjects answered questions regarding their perceived effort to walk. Some subjects also agreed to a walking test. The test involved walking 100 m at self-selected slow and fast speeds with each prosthesis. Then, subjects walked at slow and fast speeds on a programmed treadmill.

Study Population: Eighteen healthy, transfemoral amputees received an IP from the researchers. Of the 18 subjects, 3 were dual amputees. Researchers excluded 2 subjects: one reverted to his original prosthesis and another subject had pain in his natural foot. Of the 16 remaining subjects, 6 agreed to treadmill tests. All 16 subjects received questionnaires.

Results: Use of the different knees did not result in increased oxygen consumption. Step length was more symmetrical with the IP than with the standard prosthesis. The 14 subjects who returned their surveys indicated that using the IP at normal and fast speeds required less effort. Users also felt walking with IP required less effort outdoors, at work, or down slopes. However, they did not report differences going up slopes or on stairs. For questions about patients' confidence that the knee would not give way, patients scored the knees similarly. Overall, users strongly preferred the IP to the standard knee.

Conclusion: Transfemoral amputees' gait is symmetrical at fast and slow speeds when using the IP.

4. The Medical Devices Agency of the National Health Service of Great Britain conducted a survey in 1994 comparing the IP to other prosthesess. (Medical 1994)

   Study Population: The evaluation included 85 above the knee amputees.

   Results: Subjects reported
   - walking faster with the IP (80%)
   - feeling less tired (80%)
   - thinking less about walking (60%)
   - wishing to continue using IP (100%)

   The following remained unchanged for subjects
   - amount of walking (70%)
   - step length (70%)
   - feeling safe when ascending stairs (100%)
   - feeling safe when descending stairs (80%)

   Subjects found it easier to
   - walk on long, level walks (100%)
   - walk around obstacles (70%)
   - sit and stand from a chair (50%)

   Conclusion: Users have the ability to walk further for less effort, and they require less concentration to achieve a satisfactory gait.

5. Taylor compared 4 prostheses: IP (IP on), IP programmed for constant damping (IP off), Mauch SNS hydraulic swing phase controlled (MAUCH), and Endolite pneumatic swing phase controller. (Taylor 1996)

   The subject had 5 weeks to accustom himself to each prosthesis. Then, the subject walked on a treadmill at 2, 2.6, and 3.2 km/h for 5 minutes each. Researchers measured oxygen uptake and heart rate at each speed and averaged the last 3 minutes of each walk. Average cadence, as measured by steps per minute, was based on the first and last 30 seconds of each walk.

   Study Population: The study included a 33-year old subject with an amputation at the proximal quarter femur level due to trauma.

   Results: An association between IP and 10% lower oxygen uptake existed at 3.2 km/h. Cadence remained constant during each walk. Investigators found substantial test-retest differences.

   Conclusion: Large variations in cadence resulted between tests contributing to variation in energy expenditure.

VI. Cost

The price of the C-Leg ranges from $40,000 to $50,000 depending on the market area.

The price of Endolite products also depends on market area. A company representative chose not to estimate a price range.

VII. Department's Experience

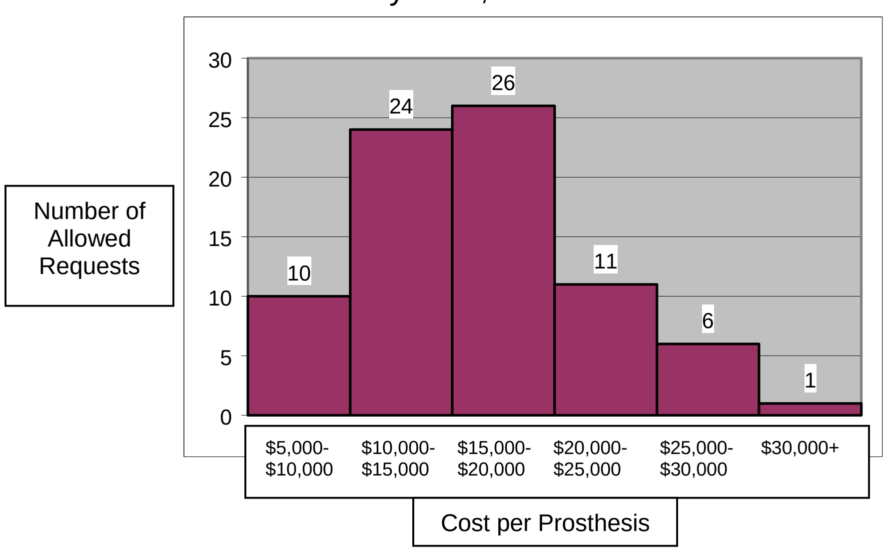
Between November 1997 and June 2002, the Department purchased 8 microprocessor-controlled knee systems ranging in price from $20,528 to $61,525 and averaging $35,760. Specific comments from workers or their practitioners about the knees were not available.

From 1992 to 2002, the department purchased 78 other prostheses under HCPCS codes L5320 and L5321. Code descriptions read:

- L5320 Above knee, molded socket, open end, SACH foot, endoskeleton system, single axis knee, including soft cover and finishing (code deleted for 2002)
- L5321 Above knee, molded socket, open end, SACH foot, endoskeleton system, single axis knee

The total prices for the knees and all additions ranged from $7,426 to $30,632 and averaged $16,606.

Number of Prostheses (L5320, L5321) Purchased by LNI,
By Cost, 1992-2002



VIII. Professional Organizations

The Amputee Coalition of America does not endorse microprocessor-controlled prostheses due to a strict, non-endorsement policy regarding products, services, and providers. (Bruce 2002)

IX. Other Payers

The Department of Veterans Affairs provides computerized lower extremity prostheses for selected patients. (Downs 2000) Patient criteria include:

- adequate cardiovascular reserve and cognitive learning ability.
- ability to ambulate at a faster than baseline rate using a standard prosthesis.
- demonstrated need for long distance ambulation (over 400 yards) at variable rates.
- demonstrated need for ambulation on uneven terrain or stairs. limited stair climbing in home or work environments is not sufficient for prescription.

Aetna does not cover microprocessor-controlled lower limb prostheses because of a lack of sufficient evidence in the literature. (Aetna 2001)

Blue Cross Blue Shield of North Carolina does not cover prosthetic appliances with microprocessors because the modification is generally not required for standard, daily activities. (BCBSNC 2002)

The Regence Group does not cover prosthetic knees controlled by microprocessors because they are not required to perform standard activities of daily living. (Regence 2002)

X. Conclusion

Peer-reviewed journals have published 4 studies of microprocessor-controlled prosthetic knees. Surveys found that the majority of subjects perceived computerized knees as favorable and preferred to keep the new knees. However, evidence of the device's ability to facilitate walking on uneven ground and stairs remains mixed. Computerized knees may reduce energy expenditure, but may not reduce the cognitive effort required for walking. Due to the small number of studies and study participants, evidence of the broad effectiveness of microprocessor-controlled prosthetic knees remains inconclusive.